

Remarks/Arguments:

With the present amendment, claims 16-18, 20-39, and 42-45 are pending. All pending claims stand rejected. Applicants herein amend claims 16, 30-34, and 42. No new matter is added. Reconsideration is requested in view of the amendments and following remarks.

Claim rejections

Claim rejections under 35 U.S.C. §103

Jackson in view of Ko

Claims 16, 21-27, 32, 34-38, and 42-45 stand rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 3,912,795 to Jackson ("Jackson") in view of U.S. Patent No. 4,249,527 to Ko et al. ("Ko"). While the Office Action does not recite claims 20 and 39 in the listing of rejected claims on page 2 of the Office Action, pages 3 and 4 infer that claims 20 and 39 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson in view of Ko. Applicants are herein addressing the rejection of claims 20 and 39 as such.

Amended independent claim 16 recites, *inter alia*, a system for delivering humidified gas to a patient. The system comprises a *supply unit configured to deliver a heated and humidified gas*. A delivery tube assembly has a delivery tube with a proximal end and a distal end. The delivery tube assembly also has a fitting positioned at said proximal end of said delivery tube and releasably coupled to said supply unit. The delivery tube assembly is configured to transfer heat to *the heated and humidified gas received from the supply unit*.

Amended independent claim 32 recites, *inter alia*, a method for delivering heated and humidified gas to a patient, said method comprising the steps of releasably connecting a fitting of a proximal end of a delivery tube to a supply unit; releasably coupling a nasal cannula to a distal end of the delivery tube; *heating and humidifying a breathing gas in the supply unit*, thereby producing a heated and humidified gas *in the supply unit*; delivering the heated and humidified gas *from the supply unit*, through the delivery tube, and to the nasal cannula for delivery to the patient; and delivering only the heated and humidified gas through the cannula.

Amended independent claim 34 recites, *inter alia*, a system for delivering heated and humidified gas to a patient. The system comprises *a supply unit that heats a breathing gas and combines the breathing gas with water vapor to form a heated and humidified gas in the supply unit*. A delivery tube is releasably coupled to the supply unit. The delivery tube is configured to transfer heat to the heated and humidified breathing gas received from the supply unit. The breathing gas is humidified *in the supply unit* by fluid that has flowed through and reverses direction in the delivery tube.

Amended independent claim 39 recites, *inter alia*, a warming and humidifying system for a breathing gas comprising a fluid supply; a means for heating the breathing gas with fluid from the fluid supply; and *a means for humidifying the breathing gas with the fluid after the fluid has insulated the breathing gas.*

Amended independent claim 42 recites, *inter alia*, a method of delivering a breathing gas to a patient, the method comprising the steps of coupling a delivery tube to a supply unit; coupling a nasal cannula to the delivery tube; *heating and humidifying the breathing gas in the supply unit; delivering the heated and humidified breathing gas from the supply unit to the delivery tube* such that the heated and humidified breathing gas flows in a first direction through the delivery tube; insulating the heated and humidified breathing gas with a fluid in the delivery tube such that the fluid flows in at least the first direction through the delivery tube as the fluid insulates the heated and humidified breathing gas; and delivering the heated and humidified breathing gas from the delivery tube to the nasal cannula for delivery to the patient.

Jackson discloses an apparatus for humidifying a gas. Jackson discloses a delivery tube 10 that includes a water chamber 18 extending along a length of tube 10. Within water chamber 18, a conduit 24 supplies water along a length of delivery tube 10 to an end 20 of chamber 18. A porous metal mesh 34 fills a space between conduit 24 and an inner surface of chamber 18. An air supply conduit 14 supplies breathing air from an air supply (not numbered). The breathing air flows through tube 10, between wall of tube 10 and water chamber 18. Water vapor passes through the wall of chamber 18 to humidify the air for breathing by a patient. See Jackson FIG. 1 and Col. 2, lines 19-52. The breathing gas is neither heated nor humidified in a supply unit and, in fact, is not heated or humidified until the breathing gas is in the delivery tube. See Jackson, Fig. 1. Additionally, as Jackson discloses heating and humidification in the delivery tube, Jackson actually teaches away from heating and/or humidification in the supply unit, as is recited in each of independent claims 16, 32, 34, and 42.

Jackson fails to disclose or suggest the claimed limitation of amended claim 16 of a supply unit that heats a breathing gas and combines the heated breathing gas with water vapor *to form a heated and humidified gas in the supply unit*; the limitation of amended claim 32 of *heating and humidifying a breathing gas in the supply unit*, thereby producing a heated and humidified gas *in the supply unit*; the limitation of amended claim 34 of *a supply unit that heats a breathing gas and combines the breathing gas with water vapor to form a humidified gas in the supply unit*; and the limitation of amended claim 42 of *heating and humidifying the*

breathing gas in the supply unit and delivering the heated and humidified breathing gas from the supply unit to the delivery tube.

Ko is cited for allegedly disclosing a releasable nasal cannula. Ko fails to make up the deficiencies of Jackson. Accordingly, Applicants respectfully submit that the proposed combination of Ko with Jackson still fails to meet the features of claims 16, 32, 34, and 42 discussed above.

Further, Jackson discloses an endotracheal tube 17 that is inserted into the user's mouth and to the user's trachea. Endotracheal tube 17 eliminates the need for a nasal cannula. Applicants respectfully submit that Jackson discloses a complete system for transmitting breathing gas from a supply unit to a patient, and one having ordinary skill in the art would therefore not have a need to look to any other reference in order to provide a device, such as a nasal cannula, to deliver heated and humidified breathing gas to a patient. Accordingly, the proposed combination of Jackson with Ko is improper.

Regarding amended claim 39, the claim includes "means for" language that must be interpreted under 35 U.S.C. §112, sixth paragraph. Therefore, claim 39 "shall be construed to cover the corresponding structure . . . described in the specification and equivalents thereof." 35 U.S.C. §112, sixth paragraph. "[T]he PTO may not disregard the structure disclosed in the specification corresponding to such language when rendering a patentability determination." *In re Donaldson Co.*, 16 F.3d 1189, 29 USPQ2d 1845 (Fed. Cir. 1994).

The Office Action alleges that Jackson discloses a supply unit which consists of elements 28, 24, 26, 18, and 34. Applicants respectfully traverse this interpretation. Jackson's elements 18, 34 are parts of a delivery tube 10, and are not parts of a supply unit. Jackson heats and humidifies his breathing gas in delivery tube 10, and not in the supply unit.

On the other hand, the specification of the present application discloses "a means for humidifying the breathing gas" as an exchanger 410 within a supply unit assembly 402. Exchanger 410 may be a cartridge 100 that is used to humidify an air stream. Cartridge 100 contains a plurality of hollow fiber membranes 135 that transport breathing air therethrough. Water flows through spaces around fiber membranes 135 and passes through pores in the membranes to deliver vaporized water to the breathing gas. Specification, page 6, line 16 - page 7, line 19. Neither Jackson nor Ko disclose or suggest the structure of a supply unit having a cartridge with hollow fiber membranes that allow water vapor to pass therethrough for humidifying a breathing gas. As discussed above, Jackson teaches the humidification of the breathing gas *in the delivery tube*, and not in the supply unit as disclosed in the present specification. Because Jackson fails to disclose or suggest the corresponding structure

described in the specification and equivalents thereof, Jackson does not include the means for humidifying the breathing gas as recited in claim 39.

Because the proposed combination of Jackson and Ko fails to disclose all of the limitations of claim 39, Applicants respectfully submit that the rejection of claim 39 is improper. Reconsideration and allowance of claim 39 are respectfully requested.

Because the proposed combination of Jackson and Ko fails to disclose or suggest all of the limitations of each of independent claims 16, 32, 34, 39, and 42, Applicants respectfully submit that the rejection of claims 16, 32, 34, 39, and 42 is improper. Claims 21-27 ultimately depend from claim 16, claims 35-38 ultimately depend from claim 34, and claims 43-45 ultimately depend from claim 42. Applicants respectfully submit that claims 21-27, 35-38, and 43-45 are all allowable over the proposed combination of Jackson and Ko for at least the same reasons set forth above with respect to claims 16, 34, and 42. Accordingly, Applicants respectfully request reconsideration and allowance of claims 16, 20-27, 32, 34, 39, and 42-45.

Jackson in view of Ko, and further in view of McComb and Koch

Claims 28-31, 33, 17, and 18 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson in view of Ko, and further in view of U.S. Patent No. 5,349,946 to McComb ("McComb") and U.S. Patent No. 6,367,472 to Koch ("Koch").

Amended independent claim 30 recites, *inter alia*, a method for delivering heated and humidified gas to a neonatal patient. The method comprises the steps of connecting a delivery tube to a supply unit configured to deliver humidified gas; coupling a nasal cannula to the delivery tube; *heating and humidifying a breathing gas in a supply unit*, thereby generating the heated and humidified gas; and delivering the heated and humidified gas from the supply unit to the neonatal patient through the delivery tube and the cannula at a flow rate of about 1 liter per minute to about 8 liters per minute and at a relative humidity in a range of about 95% to about 100%.

Amended independent claims 31 recites, *inter alia*, a method for assisting respiration in a neonatal patient comprising *heating and humidifying a breathing gas in a supply unit*; and *delivering the heated and humidified breathing gas from the supply unit to a nasal passageway of the neonatal patient through a delivery tube* and a nasal cannula at a flow rate of about 1 liter per minute to about 8 liters per minute and at a relative humidity in a range of about 95% to about 100%.

Amended independent claim 33 recites, *inter alia*, a method for delivering heated and humidified gas to a nasal passageway of a neonatal patient using a supply unit to deliver

humidified gas, a delivery tube assembly configured to transfer heat to the humidified gas received from the supply unit and having a delivery tube and a fitting connected to the supply unit, and a nasal cannula coupled to the delivery tube assembly. The method comprises the steps of *heating and humidifying a breathing gas in the supply unit*, thereby producing a heated and humidified gas in the supply unit; and *delivering the heated and humidified gas from the supply unit, through the delivery tube assembly* and into the nasal cannula at a flow rate of about 1 liter per minute to about 8 liters per minute and at a relative humidity in a range of about 95% to about 100%.

Jackson and Ko are discussed above. McComb is cited for allegedly disclosing a supply unit configured to deliver humidified gas at flow rates between 3 to 150 liters per minute. Koch is cited for allegedly disclosing humidification of air in the range of 90% to 100%.

Applicants note that McComb discloses a humidifier 24 and that Koch discloses a humidifier 1. Applicants respectfully submit, however, that the delivery tube of Jackson, which heats and humidifies breathing gas downstream of a supply unit, eliminates the need to look to either McComb or Koch to humidify breathing gas in a supply unit. Assuming, *arguendo*, that one were to attempt to combine either the McComb or Koch references with Jackson, the resulting device would provide humidification of the breathing gas both in the supply unit and in the delivery tube. Such over-humidification may result in undesired rainout, which is the formation of particulate water droplets in the breathing gas. The problem of rainout is recognized by McComb as an unwanted result of over-humidification. See McComb, Col. 6, lines 11-14.

Further, because each of McComb and Koch teaches to humidify breathing gas in a supply unit, one of ordinary skill in the art, having either the McComb or Koch references in front of them, would not need to combine either of these references with Jackson to humidify the breathing gas. Therefore, the proposed combination of Jackson with McComb and Koch, as well as Ko, is improper

Claims 17, 18, 28, and 29 ultimately depend from claim 16. Claims 17 and 18 add flow rate limitations and claims 28 and 29 add supplemental liquid limitations. As discussed above with respect to claims 30, 31, and 33, McComb still teaches away from combining his device with a delivery tube. Because the proposed combination is improper, the Office Action fails to establish a *prima facie* case of obviousness with regard to claims 17, 18, 28, and 29, Applicants respectfully submit that claims 17, 18, 28, and 29 are allowable over the proposed combination of Jackson, Ko, McComb, and Koch for at least the same reasons set forth above.

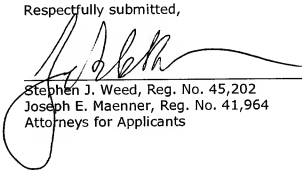
Because the proposed combination of Jackson, Ko, McCombs, and Koch fails to disclose or suggest all of the limitations of claims 28-31, 33, 17, and 18, Applicants respectfully submit that the rejection of claims 28-31, 33, 17, and 18 is improper. Accordingly, Applicants respectfully request reconsideration and allowance of claims 28-31, 33, 17, and 18.

Conclusion

In light of the above amendments and remarks, Applicants respectfully submit that claims 16-18, 20-39, and 42-45 are in condition for allowance. Prompt reconsideration and allowance is respectfully requested.

The Examiner is invited to contact the undersigned to discuss the amendments and remarks made herein.

Respectfully submitted,



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